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IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

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RANCHERS CATTLEMEN ACTION LEGAL FUND
UNITED STOCKGROWERS OF AMERICA,

Plaintiff-Appellee,

v.

UNITED STATES DEPARTMENT OF AGRICULTURE,
ANIMAL AND PLANT HEALTH INSPECTION SERVICE, and MIKE JOHANNNS,
in his capacity as the Secretary of Agriculture,

Defendants-Appellants.

On Appeal from the United States District Court
for the District of Montana

BRIEF FOR AMICI CURIAE NATIONAL CATTLEMEN'S BEEF ASSOCIATION,
AMERICAN FARM BUREAU FEDERATION, NATIONAL PORK PRODUCERS COUNCIL,
29 STATE CATTLEMEN'S ASSOCIATIONS, 18 STATE FARM BUREAUS,
AND 9 INDIVIDUAL CATTLE PRODUCERS SUPPORTING
DEFENDANTS-APPELLANTS AND VACATUR

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**BRIEF FOR AMICI CURIAE NATIONAL CATTLEMEN'S BEEF ASSOCIATION, et
al. SUPPORTING DEFENDANTS-APPELLANTS AND VACATUR**

STATEMENT OF INTEREST OF AMICI CURIAE

Amici are the National Cattlemen's Beef Association ("NCBA"), the American Farm Bureau Federation ("AFBF"), the National Pork Producers Council, 29 state cattlemen's associations, 18 state Farm Bureaus, and 9 individual cattle producers. See Addendum hereto. Amici represent and include a broad range of American farmers and ranchers, whose economic, political, and social interests the amici organizations serve to promote. NCBA is the largest organization representing the

Nation's cattle industry; AFBF represents some 5.6 million farm families across the country. Collectively, the States represented by the state amici organizations are home to more than 85% of the Nation's cattle producers and 75% of the Nation's cattle herds.

Amici have a direct and substantial interest in this case. At issue is the scientific validity of a Final Rule promulgated by the United States Department of Agriculture ("USDA") designating Canada as a minimal-risk region for bovine spongiform encephalopathy ("BSE") and allowing the importation of certain Canadian cattle and beef products. See 70 Fed. Reg. 460 (Jan. 4, 2005). As entities and individuals engaged in and dedicated to promoting U.S. agriculture, amici have a significant interest in ensuring that food safety decisions are based on sound science, and many have taken an active role in the collection and dissemination of information concerning BSE. NCBA, for example, currently maintains on behalf of the national beef checkoff program a website providing background information and the latest updates on BSE. See www.bseinfo.org.

As the website explains, numerous science-based mitigation measures are in place in the United States to prevent the spread of BSE and to ensure the safety of U.S. beef. As a result, U.S. consumer confidence in the safety of U.S. beef remains high. Recent consumer research indicates that, despite the December 2003 discovery of a BSE-infected cow of Canadian origin in

Washington State, 93% of consumers remain confident in the safety of U.S. beef. Following that discovery, however, more than 70 foreign countries closed their markets to U.S. beef exports. Industry experts conservatively estimate that BSE has cost the U.S. cattle industry over \$4 billion in lost exports. Although about 35% of those markets have since reopened, two of the largest markets -- Japan and Korea -- remain closed. Those markets are unlikely to reopen if questions are raised about the safety of U.S. beef.

The preliminary injunction issued in this case raises such questions. As explained below, the Final Rule is based on sound science that demonstrates that the safeguards in place in both the United States and Canada are effective and will ensure the continued safety of U.S. beef. In rejecting that evidence and enjoining the Rule, the District Court effectively held that the mitigation measures taken by Canada -- which are the same as those taken by the United States -- are insufficient to mitigate the risk of BSE. Its decision therefore creates the false impression that the mitigation measures in place in the United States are ineffective, and thus threatens to undermine U.S. consumer confidence in the safety of U.S. beef and to discourage foreign nations from opening their markets to U.S. beef exports. The preliminary injunction places the interests of the U.S. cattle industry in serious jeopardy, and should be vacated.

STATEMENT OF FACTS

Bovine Spongiform Encephalopathy ("BSE"). BSE is a neurological disorder afflicting cattle that is believed to result from the transmission of an abnormal form of animal protein. 70 Fed. Reg. at 461. BSE is spread to cattle through the consumption of feed containing protein from BSE-infected ruminants. Id. at 461, 486. BSE was first diagnosed in the United Kingdom in 1986. Id. at 461. Since then, there have been about 187,000 confirmed cases of BSE in cattle worldwide. Id. Over 95% of all BSE cases have occurred in the United Kingdom, where the epidemic peaked in 1992-1993. Id. at 462. Since the adoption of mitigation measures by the United Kingdom -- most notably a feed ban prohibiting the use of mammalian meat-and-bone meal in cattle feed -- the annual incidence of BSE in the United Kingdom has fallen dramatically. Id.

Variant Creutzfeld-Jakob disease ("vCJD") is a neurodegenerative human disease which has been linked to exposure to BSE. Id. Since vCJD was first diagnosed in 1996, about 150 cases of the disease have been identified. Id. The vast majority of these cases have either occurred in the United Kingdom or have been linked to exposure that occurred in the United Kingdom, and all cases have been linked to exposure in countries with native cases of BSE. Id. Some studies estimate that more than 1 million cattle may have been infected with BSE during the epidemic in the United Kingdom, indicating that human

exposure to BSE at that time was quite high. Id. Thus, the fact that only about 150 cases of vCJD have been identified suggests a substantial species barrier that may protect humans from widespread illness from exposure to BSE. Id.

Risk Mitigation Measures Implemented In The United States.

Over the past 15 years, the United States has taken numerous steps to prevent the introduction and spread of BSE and to prevent BSE from entering the human food supply, including:

- **Import Controls.** In 1989, the United States began prohibiting the importation of cattle and most beef products from countries where BSE is known to exist, such as the United Kingdom. Id. In 1997, the United States extended the prohibition to countries at undue risk of BSE, including all European countries. Id.
- **Surveillance.** Since 1990, the United States has conducted testing of the Nation's cattle herds, targeting high-risk populations -- i.e., animals exhibiting clinical signs of BSE, non-ambulatory animals, and those that have died on the farm. Id. at 476. Experience in the United Kingdom and Europe has shown that targeting high-risk cattle is the method most likely to identify BSE. Id. at 484, 490. In June 2004, the United States implemented an enhanced surveillance program. Id. at 475-476, 490. As of December 2004, more than 136,000 cattle had been tested, all with negative results. Id. at 490.
- **Feed Ban.** In August 1997, the United States instituted a ban prohibiting the use of most mammalian protein in cattle feed. Id. at 512. Because BSE is spread to cattle through the consumption of feed containing BSE-contaminated protein, a feed ban is "[a] crucial element in preventing the spread and establishment of BSE." Id. at 467. Inspections of domestic feed manufacturers have verified a high level of compliance with the ban. Id. at 466.
- **Removal of SRMs.** Since January 2004, the United States has required the removal at slaughter of certain cattle

tissues designated "specified risk materials" (or "SRMs") and prohibited their use in human food. Id. at 465. SRMs are primarily central nervous system tissues and include the brain, skull, eyes, spinal cord, and parts of the vertebral column of cattle 30 months of age or older, and the tonsils and distal ileum of the small intestine of all cattle. Id. Studies have identified SRMs as the specific tissues where the majority of infectivity appears to reside. Id. at 463. The removal of SRMs at slaughter effectively mitigates the BSE risk to humans from cattle that pass both ante-mortem and post-mortem inspections. Id. at 465.

- **Additional Measures.** Since January 2004, the United States has also prohibited from use in human food all non-ambulatory cattle and all mechanically separated beef, which may contain central nervous system tissues originally connected to the bone, and has also prohibited the use of penetrative captive bolt stunning devices that may force fragments of central nervous system tissue into the circulatory system of stunned cattle where the fragments may become lodged in edible tissues. Id. at 466.

BSE Regional Risk Classifications. The Office International des Epizooties ("OIE") (also known as the World Organization for Animal Health) is recognized by the World Trade Organization as the international authority responsible for the development and review of standards, guidelines, and recommendations with respect to animal health and diseases, including BSE. Id. at 463. In establishing standards and guidelines, the OIE draws on the expertise of international veterinary and other scientific experts. Id. at 477. The United States is a member of the OIE, and has been actively involved in the development of OIE standards and guidelines for BSE. Id. at 463.

The OIE currently recognizes five BSE regional risk classifications. Id. For each classification, the OIE

recommends different export conditions for animals and animal products, and provides for trade under certain conditions even with regions considered high-risk. Id. OIE's risk classifications are based on an analysis of a number of factors, including import controls, incidence, surveillance, and feed restrictions. Id. Among the risk classifications recognized by OIE is a minimal-risk category. Id.

The Final Rule. On January 4, 2005, USDA promulgated a Final Rule establishing a minimal-risk region category and setting forth conditions for the importation of certain ruminants and ruminant products from regions that meet the science-based criteria for attaining minimal-risk status. Id. at 460. The rule also classified Canada as a minimal-risk region. Id. 1/

As USDA explained, the standards for classifying a region as minimal risk are based on OIE guidelines. Id. at 464, 470. Consistent with OIE standards, regions eligible for such status include those in which a BSE-infected animal has been diagnosed, but in which measures have been taken that make it unlikely that BSE would be introduced from that region into the United States. Id. at 462. To qualify as a BSE minimal-risk region, a region

1/ On May 20, 2003, a BSE-infected cow was discovered in Canada. Id. Prior to that date, there had been no restrictions on Canadian imports of cattle or beef products. Following the discovery of the BSE-infected cow, the United States placed Canada on the list of countries where BSE is known to exist and prohibited Canadian imports of cattle and most beef products. The Final Rule thus allows the resumption of certain Canadian imports of cattle and beef products.

must maintain, and in the case of a region where BSE has been detected, must have had in place prior to the detection of BSE, risk mitigation measures adequate to prevent the spread or establishment of BSE, including:

- Import controls sufficient to minimize the possibility of infected animals and animal products being imported into the region;
- Surveillance at levels that meet or exceed OIE guidelines;
- An effectively enforced feed ban. [Id. at 463; 9 C.F.R. § 94.0.]

In regions where BSE has been detected, the region must also have conducted an epidemiological investigation sufficient to confirm the adequacy of measures to prevent the spread of BSE, and must have taken additional mitigation measures, as necessary, to prevent the spread of BSE. 70 Fed. Reg. 463. Whether a region ultimately qualifies for minimal risk status, however, depends on "the overall effectiveness of control mechanisms in place." Id. (emphasis added).

USDA's decision to establish a minimal-risk category was based on a number of considerations, including a "significant amount of research" which provides "a sound and compelling scientific basis" for the Final Rule. Id. "[B]oth research studies and field epidemiological experience have demonstrated effective control measures to prevent spread of this disease." Id. In particular, "[e]arly epidemiological work identified contaminated feed as the primary method of spread of the disease

between animals," and "[o]ngoing studies have identified specific tissues where the majority of infectivity appears to reside, so that these tissues can be removed from the food chain." Id.

The decision to classify Canada as a minimal-risk region was also based on a number of factors. Id. at 486. To begin with, Canada has taken virtually the same steps as the United States to prevent the spread and establishment of BSE, including:

- **Import Controls.** In 1990, Canada began prohibiting the importation of cattle from the United Kingdom and the Republic of Ireland. In 1994, Canada extended the ban to all countries where BSE had been detected in native cattle. In 1996, Canada made the ban even more restrictive by prohibiting the importation of live ruminants from any country that had not been recognized as BSE-free following a comprehensive risk assessment. Id. at 467.
- **Surveillance.** In 1992, Canada began testing its adult cattle population of approximately 5.5 million, targeting high-risk cattle. Current OIE guidelines recommend annual sampling of at least 300 high-risk cattle over 30 months of age within a population of 5 million and 336 cattle within a population of 7 million. Canada, which in 2004 tested over 15,800 head of cattle over 24 months of age, has for the past seven years met or exceeded OIE standards of surveillance. Id. at 468. In 2005, Canada plans to test at least 30,000 animals. Id. at 469.
- **Feed Ban.** In August 1997, Canada instituted a feed ban equivalent to the feed ban in place in the United States. Inspections of Canadian feed manufacturers have verified a high level of compliance with the ban. Id. at 468-469, 476.
- **Removal of SRMs.** Since July 2003, Canada has required the removal of SRMs at slaughter consistent with OIE guidelines. Id. at 465, 496.
- **Tracking and Tracing.** Canada has determined that a total of 182 cattle were imported from the United Kingdom between 1982 and 1990, and has purged those animals from

its herds. Id. at 467, 514. Canada has also recently implemented enhanced measures for tracking and tracing cattle. Id. at 468.

- **Epidemiological Investigations.** Following the discoveries of BSE-infected cows of Canadian origin in May and December 2003, Canada immediately launched comprehensive epidemiological investigations which concluded that both infected animals had been born prior to the implementation of Canada's feed ban and were most likely exposed to BSE before the ban's implementation. Id. at 468-469. The investigations also concluded that the most likely source of infection was feed containing protein from an infected animal imported from the United Kingdom between 1982 to 1989. Id. All animals potentially exposed to BSE from the same sources were destroyed, and all tested negative for BSE. Id.

In concluding that these mitigation measures were effective, USDA compared Canada's BSE incidence level (0.4 cases per million head of cattle over 24 months of age in 2003) with OIE standards for minimal risk (less than 2 cases per million head of cattle over 24 months of age during each of the last four consecutive 12-month periods). Id. at 464, 512.

USDA's decision was also based on a risk assessment prepared by the Animal and Plant Health Inspection Service ("APHIS") entitled "Risk Analysis: BSE Risk from Importation of Designated Ruminants and Ruminant Products from Canada into the United States." Id. at 464. That assessment drew on a number of sources, including the scientific literature, epidemiological investigations, and quantitative analyses. Id. In particular, the assessment drew on an independent quantitative analysis prepared by the Harvard Center for Risk Analysis ("HCRA") and the

Center for Computational Epidemiology at Tuskegee University (the "Harvard-Tuskegee Study"). Id.

The Harvard-Tuskegee Study was commissioned by USDA to assess the risk of BSE spreading if introduced in the United States. Id. at 466-467. The study reviewed available scientific information related to BSE, assessed pathways by which BSE could potentially spread in the United States, and identified measures that could be taken to protect human and animal health. Id. at 467. The study concluded that, even if BSE were introduced in the United States, the mitigation measures already in place would make it unlikely that BSE would spread or become established. Id. The two most effective measures identified by the study were import controls and the feed ban. Id. 2/

After the May 2003 discovery of a BSE-infected cow in Canada, HCRA assessed the implications of a then-hypothetical introduction of BSE into the United States from Canada, using the same model developed for the Harvard-Tuskegee Study. That assessment, entitled "Evaluation of the Potential Spread of BSE in Cattle and Possible Human Exposure Following the Introduction of Infectivity into the United States from Canada," confirmed the conclusions of the Harvard-Tuskegee Study -- "that a very low risk exists of BSE becoming established or spreading should it be

2/ Notably, the Harvard-Tuskegee Study was released in 2003, before the United States began requiring the removal of SRMs. Id. at 467.

introduced into the United States." Id. Following the receipt of comments on the Proposed Rule, USDA asked HCRA to respond to comments pertaining to the Harvard-Tuskegee Study, including those submitted by plaintiff ("R-CALF"). Id. HCRA responded in a June 2004 memorandum known as the "Cohen and Gray memorandum." Id. The memorandum updated the model used in the Harvard-Tuskegee Study and concluded that, even under worst case conditions, BSE would be unlikely to spread if it were introduced into the United States. Id. at 467, 509.

Finally, USDA relied on the additional mitigation measures imposed by the Final Rule itself. Id. at 486. Few cases of BSE have been found in cattle under 30 months of age, and those cases have occurred in countries with significant levels of infectivity, such as the United Kingdom. Id. at 483, 512. Even in the United Kingdom, no case of BSE has been found in an animal under 30 months of age since 1996. ER 319. The Final Rule prohibits the importation of cattle over 30 months of age, and permits the importation of cattle under 30 months of age only for immediate slaughter or for feeding prior to slaughter. Id. at 512; 9 C.F.R. § 93.436. These additional safeguards further protect against the spread of BSE and further ensure the safety of the human food supply. 70 Fed. Reg. 485-486.

ARGUMENT

THE FINAL RULE IS BASED ON SOUND SCIENCE AND IS THE PRODUCT OF REASONED DECISIONMAKING

The District Court enjoined the Final Rule on the ground that R-CALF had shown a substantial likelihood of prevailing on the merits of its claims. That ruling is erroneous and cannot stand. R-CALF's principal claim is that the Final Rule was promulgated in violation of the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 551 et seq. To prevail on that claim, R-CALF must show that the Final Rule was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." Id. § 706(2)(A). R-CALF's burden is a heavy one, for judicial review of agency action under the APA is "highly deferential," Sioux Valley Rural Television, Inc. v. FCC, 349 F.3d 667, 674 (D.C. Cir. 2003), especially where, as here, the agency has made a decision "within its area of special expertise, at the frontiers of science." Baltimore Gas & Elec. Co. v. Natural Res. Def. Council, Inc., 462 U.S. 87, 103 (1983).

So long as the agency "considered the relevant factors and articulated a rational connection between the facts found and the choice made," its decision must be upheld. Id. at 105. Even where the evidence before the agency is susceptible to more than one rational interpretation, "a reviewing court may not substitute its judgment for that of the agency." Hensala v.

Department of the Air Force, 343 F.3d 951, 955-956 (9th Cir. 2003) (emphasis added).

In holding that R-CALF is likely to prevail on the merits of its APA claim, the District Court failed to adhere to these basic principles. Instead of affording the agency the substantial deference it was due, the court ignored the agency's explanation for its decision and the scientific evidence and expert opinion on which it was based, repeatedly substituted its judgment for that of the agency's science-based evaluation, and adopted R-CALF's unsupported assertions wholesale. That was error, and the resulting order granting the preliminary injunction should be vacated.

A. The Final Rule Is Based On A Thorough Assessment Of Its Impact On Human Health.

The District Court first concluded that R-CALF is likely to prevail on its claim that the Final Rule is arbitrary and capricious because USDA purportedly failed to adequately assess the impact of the Final Rule on human health. See Op. 8-10. In the court's view, USDA "fail[ed] to conduct a proper risk assessment," and further failed to "provide not only its conclusion that its action carries an acceptable risk to public health, but also the specific basis for that conclusion and the data on which each of the agency's critical assumptions is based." Op. 9-10. The court's holding, however, is untenable.

In the preamble to the Final Rule, USDA spent more than a dozen pages specifically discussing its risk analysis and the impact of the Final Rule on human health. See 70 Fed. Reg. 504-517. USDA concluded that, as a initial matter, "it is unlikely that infectious levels of BSE would be introduced into the United States from Canada." Id. at 505. That conclusion was based on "multiple factors," including (1) Canada's low BSE incidence rate, coupled with its active surveillance program -- both of which satisfy and exceed OIE guidelines for minimal risk; (2) other mitigation measures in place in Canada, including import controls and a feed ban; and (3) the additional mitigation measures imposed by the Final Rule itself, including the prohibition on imports of cattle over 30 months of age. Id. at 505-506.

Significantly, however, USDA also concluded that, "even if the BSE agent were introduced into the United States, it would be extremely unlikely to enter commercial animal feed and thereby infect U.S. cattle or to result in human exposure to the BSE agent." Id. at 505 (emphases added). As the agency explained, that conclusion was based on (1) the mitigation measures in place in the United States, and (2) APHIS's risk assessment, which in turn drew on a number of sources, including the Harvard-Tuskegee Study, a "quantitative analysis of the risk of BSE spreading if introduced into the United States." Id. at 465, 505. See supra at 11.

As noted, the Harvard-Tuskegee Study concluded that, even if BSE were introduced in the United States, it would be "extremely unlikely to become established in the United States." Id. at 506. Significantly, the study's conclusions were "based on conditions as they existed in 2001, before safeguards implemented recently by [the United States], including prohibitions on the use of air injection stunning devices at slaughter and prohibitions on the use of nonambulatory cattle and SRMs in human food." Id. "These newly implemented safeguards * * * make[] it far less likely that even small amounts of infective tissue would reach the human food supply and be available for human consumption." Id. (emphasis added).

APHIS's risk assessment was also based on the HCRA analysis conducted after the May 2003 discovery of a BSE-infected cow in Canada. That analysis "confirmed the conclusions of the earlier Harvard-Tuskegee Study -- namely, that a very low risk exists of BSE becoming established or spreading should it be introduced into the United States." Id. at 467. In addition, the assessment relied on the Cohen and Gray memorandum, which updated the Harvard-Tuskegee Study model using worst case values and reported "even lower estimates of risk than previously predicted." Id. at 507. See id. at 508-509. Notably, those analyses, too, reached such conclusions before the implementation of the "recently strengthened safeguards * * * that would provide

further increases in protection for human and animal health."
Id. at 511.

The District Court purported to fault USDA for failing to "perform a quantitative [risk] assessment." Op. 9 (emphasis added). But the court completely overlooked that USDA had in fact relied on quantitative risk assessments, "including the Harvard-Tuskegee Study's quantitative analysis of the risk of BSE spreading if introduced into the United States." 70 Fed. Reg. 505. (emphasis added) The court took issue with the Harvard-Tuskegee Study because it did not assess "the risk of consumer[s] contracting vCJD from consuming Canadian beef." Op. 9. But again, the court overlooked that the study specifically concluded that, even in the unlikely event that BSE were introduced in the United States, there is an "extremely small potential for human exposure." 70 Fed. Reg. at 507.

Such a small potential for exposure does not "present[] a genuine risk of death for U.S. consumers," as the District Court erroneously assumed. Op. 9. As USDA noted, "despite estimates that more than 1 million cattle may have been infected with BSE during the course of the epidemic in the United Kingdom, * * * only 150 probable and confirmed cases of vCJD have been identified worldwide." 70 Fed. Reg. 505. That data "suggests a substantial species barrier that may protect humans from widespread illness due to ingesting BSE-contaminated meat," and thus "that it is unlikely that there would be any measurable

effects on human health from small amounts of infectivity entering the food chain." Id.

B. Canada's Incidence Rate Is Well Below International Standards For Minimal-Risk Regions.

The District Court also held that R-CALF is likely to prevail on its claim that USDA failed to support its conclusion that the incidence of BSE in Canada is "low" or "minimal." See Op. 10-12. To the contrary, that conclusion was based on OIE guidelines, which represent a broad international scientific consensus. As USDA explained, "[t]he threshold for incidence set by OIE for BSE minimal-risk regions is less than 2 cases per million cattle over 24 months of age during each of the last four consecutive 12-month periods." 70 Fed. Reg. at 512 (emphases added). The Canadian population of cattle over 24 months of age is 5.5 million. Id. In 2003, two BSE-infected cows of Canadian origin were discovered. As USDA explained, that translates into only about 0.4 cases per million cattle over 24 months of age during one of the last four consecutive 12-month periods at the time the Final Rule was promulgated. Id.

The District Court held that "USDA's assumption that the incidence of BSE in Canada is minimal or very low is inconsistent with the discovery of BSE in four animals from Alberta in a relatively short time." Op. 11. But even when the two most recent cases of BSE are taken into account, the result is still only about 0.4 cases per million cattle over 24 months of age

during two of the last four consecutive 12-month periods. See Ferguson Decl. ¶ 8 (.33 cases per million in 2003 and .36 cases per million during the last 12-month period).

Thus, Canada's incidence rate is "well within the OIE guidelines for BSE minimal risk." 70 Fed. Reg. 510. As USDA explained, "the number [of detected cases] may be taken as a strong indication in countries with active surveillance that the mitigation measures in place to prevent the introduction and spread of BSE are working, thus prevalence is likely to be low." Id. at 512. That, USDA concluded, is the case in Canada, which "has conducted surveillance for BSE since 1992 and has met or exceeded OIE guidelines for surveillance since 1995," and which has adopted effective mitigation measures, including strict import controls and a "feed ban[]" equivalent to that of the United States, on the same date as the United States in August 1997." Id. Indeed, all four BSE-infected cows of Canadian origin were born before or shortly after the implementation of Canada's feed ban. Id. at 510; 70 Fed. Reg. 18,252, 18,255 (Apr. 8, 2005). With the feed ban in place now for nearly eight years, it is far "more likely that the incidence of BSE is decreasing in Canada rather than increasing." Id. at 510.

The District Court simply ignored the fact that Canada's incidence rate is well below OIE standards for minimal risk. The court appeared to believe that Canada's incidence rate is greater than 5.5 cases per million cattle. See Op. 11. As just

explained, however, that is incorrect. The District Court's erroneous assumption appears to be based on a flawed analysis submitted by R-CALF, which improperly extrapolated data from one geographic area in Canada to the whole country, and which failed to calculate incidence rates over a consecutive 12-month period. See Ferguson Decl. ¶ 8.

Similarly flawed is the District Court's conclusion that "the evidence indicates that Canada has not conducted sufficient testing for BSE to accurately assess the rate of BSE infection in Canada." Op. 10. That erroneous conclusion appears to be based on the fact that Canada has tested fewer cattle than the United States. See id. As noted, in 2004 Canada tested more than 15,800 head of cattle. 70 Fed. Reg. at 476. Canada has announced plans to test approximately 30,000 head of cattle in 2005, whereas the United States has announced plans to test more than 200,000 head of cattle. Id. As USDA explained, however, "[b]ecause the cattle population in Canada is much smaller than the cattle population in the United States, Canada does not need to test the same number of animals as the United States." Id. Thus, "[s]urveillance testing of 30,000 animals in Canada is equivalent to the U.S. target of sampling 240,000 to 300,000 animals." Id. Moreover, for the past 7 years, testing in Canada has met or exceeded OIE guidelines, which call for at least 300 samples per year from high-risk animals within an adult cattle

population of 5 million, and 336 samples per year within an adult cattle population of 7 million. See id.

C. Canada's Feed Ban Is An Effective Mitigation Measure.

The District Court also erroneously held that R-CALF is likely to prevail on its claim that USDA unjustifiably relied on Canada's feed ban in promulgating the Final Rule. See Op. 12-15. As an initial matter, the District Court erred in considering the validity of the Final Rule in terms of a single mitigation measure. As USDA emphasized, the feed ban "is not the sole mitigation [measure]" on which the Final Rule is based. 70 Fed. Reg. at 515 (emphasis added). Rather, the Final Rule is based on a multitude of science-based factors, including the "sum total" of all of the mitigation measures in place in both Canada and the United States. Id. at 510. See, e.g., id. at 463, 465, 470, 486, 528.

In any event, the District Court's conclusion that the feed ban is not an effective mitigation measure is entirely without basis. As USDA noted, "[t]he best scientific evidence * * * is that BSE is spread primarily by contaminated feed and that prohibiting the feeding of ruminant-origin protein to ruminants prevents disease spread." Id. at 514. Indeed, "oral ingestion of feed contaminated with BSE is the only documented route of field transmission of the disease." Id. at 486 (emphasis added). Because the Final Rule prohibits the importation of cattle over 30 months of age -- and thus cattle born before Canada's feed ban

was implemented -- it is extremely unlikely that BSE-infected cattle would ever be imported into the United States.

The District Court itself acknowledged that "[t]here is a general consensus among experts that the most important means of preventing the spread of BSE in cattle is limitations on cattle feed." Op. 12 (emphasis added). Yet the District Court immediately proceeded to second-guess that broad scientific consensus and USDA's reliance upon it, concluding that "[t]hese assumptions are subject to uncertainty," and that "there is no conclusive scientific proof that [the consumption of contaminated feed] is the only route" through which BSE is transmitted. Id.

That was error. Agencies are entitled to rely on the views of experts of their own choosing, and it was not for the District Court to substitute its judgment for that of USDA by rejecting the expert opinions on which the agency relied. See Marsh v. Oregon Natural Res. Council, 490 U.S. 369, 378 (1989) ("an agency must have discretion to rely on the reasonable opinions of its own qualified experts") (emphasis added).

In any event, the District Court's reasons for rejecting the "general consensus among experts" are unfounded. The court concluded that both the Canadian and U.S. feed bans "are not complete as they allow bovine blood to be used in cattle feed." Op. 14. Although USDA noted that "recent scientific studies have indicated that blood may carry some infectivity for BSE," the agency emphasized that "those studies have concerned blood

transfusions in animals," not bovine blood in cattle feed. 70 Fed. Reg. at 491. Moreover, those studies involved transmission in sheep, not cattle. See Engeljohn Decl. ¶ 16. The scientific consensus is that findings concerning the transmission of infectivity through the blood of sheep cannot be extrapolated to cattle. Id. The same is true with respect to saliva. See id. at ¶ 17.

The court also questioned the effectiveness of Canada's feed ban because, like the U.S. ban, it allows the use of rendered animal fat in cattle feed. Op. 14. As USDA explained, however, tallow -- i.e., rendered animal fat -- does not create a risk of BSE if it is protein-free. 70 Fed. Reg. at 501. Because Canada's ban allows animal fat to be used in cattle feed only if it is protein-free, the ban sufficiently protects against the spread of BSE. Id. at 491.

The District Court also noted that OIE guidelines for minimal risk recommend a feed ban that has been in place for at least 8 years, and that Canada's feed ban has been in place for less than 8 years. Op. 12. (Both the United States and Canada will hit the 8-year mark in August 2005). But the court overlooked that the Final Rule prohibits the importation of cattle over 30 months of age, and thus that cattle imported into the United States will have been born long after Canada's feed ban went into effect. As a result, Canada's feed ban of nearly

eight years is more than sufficient to mitigate the risk of BSE spreading to the United States.

The District Court also surmised that each of the BSE-infected Canadian cows could have been become infected after the implementation of the feed ban. Op. 13. That erroneous conclusion is based on the flawed assumption that the incubation period for BSE in Canada is 4.2 years. See id. Research indicates that the incubation period for BSE is linked to the amount of the infectious dose received -- i.e., the larger the infectious dose, the shorter the incubation period. 70 Fed. Reg. at 483. BSE in younger cattle indicates significant exposure to BSE. Id. During the BSE epidemic in the United Kingdom, when there was a high level of circulating infectivity, the mean incubation period was 4.2 years. Ferguson Decl. ¶ 11. The BSE-infected Canadian cows were older animals (between 6 and 8 years), indicating lower exposure to BSE and thus a longer incubation period. Id. Thus, those cows were most likely infected prior to or shortly after the implementation of the feed ban, as epidemiological investigations conducted by Canada and the United States concluded. See 70 Fed. Reg. 468-469; 70 Fed. Reg. 18,255, 18,258.

Finally, the District Court suggested that Canada's feed ban cannot be considered effective because one of the BSE-infected Canadian cows was born shortly after the implementation of the ban. Op. 13. At the time the ban went into effect, however,

existing stocks of feed were permitted to be depleted. 70 Fed. Reg. 18,258. Moreover, the feed ban likely took some time to be completely implemented throughout the feed manufacturing industry. Id. Thus, the discovery of a BSE-infected cow born shortly after the feed ban does not demonstrate that the ban is ineffective. In recent years, Canadian feed manufacturers have maintained high levels of compliance with the ban. 70 Fed. Reg. at 515.

D. The SRM-Removal Requirement Is An Effective Mitigation Measure.

The District Court also held that R-CALF is likely to prevail on its claim that USDA arbitrarily assumed that the SRM-removal requirement "will shield consumer[s] from exposure to BSE." Op. 15. Again, the court erred in considering the validity of the Final Rule in light of a single mitigation measure, as the rule is based on the overall effectiveness of all the mitigation measures in place in both the United States and Canada. See supra at 21.

In any event, as USDA explained, SRMs are the "specific tissues where the majority of infectivity appears to reside." 70 Fed. Reg. 463. That conclusion is based on numerous scientific studies in the administrative record which demonstrate that BSE infectivity resides in SRMs and is not found in tissues such as muscle or organs such as the liver. See, e.g., AR 11,921, 11,935, 11,944-945, 11,951, 12,502; see also 70 Fed. Reg. at 491.

Those studies have been bolstered by a recent study which confirms that BSE infectivity resides in SRMs. See G.A.H. Wells, et al., "Pathogenesis of Experimental Bovine Spongiform Encephalopathy: Preclinical Infectivity in Tonsil and Observations on the Distribution of Lingual Tonsil in Slaughtered Cattle," 156 Veterinary Record 401 (Mar. 26, 2005).

In view of this growing body of scientific evidence, the removal of SRMs at slaughter is widely considered to be one of the most effective means of minimizing the risk of human exposure to BSE. Engeljohn Decl. ¶ 7; Ferguson Decl. ¶ 13. Accordingly, the Final Rule is reasonably based in part on the effectiveness of the SRM-removal requirements in place in the United States and Canada -- both which are consistent with OIE guidelines. 70 Fed. Reg. at 496.

The District Court noted that R-CALF had submitted studies purporting to demonstrate that "it is no longer reasonable to presume that there is no risk of exposure to BSE infectious agents once an SRM removal requirement is in place." Op. 15. None of those studies, however, involved BSE in cattle. See Cox Decl. ¶ 17; Ferguson Decl. ¶ 13. As USDA has explained, data involving similar diseases in other animals cannot be extrapolated to BSE in cattle. Ferguson Decl. ¶ 13. Thus, while USDA's animal health and food safety experts "carefully considered" the studies submitted by R-CALF, they concluded that

those studies provided no scientific basis for altering the Final Rule. Engeljohn Decl. ¶ 18.

As this Court has held, "[a]gencies are normally entitled to rely upon the reasonable views of their experts over the views of other experts." Ground Zero Center For Non-Violent Action v. United States Dep't of Navy, 383 F.3d 1082, 1090 (9th Cir. 2004) (emphases added). See also Marsh, 490 U.S. at 378 ("When specialists express conflicting views, an agency must have discretion to rely on the reasonable opinions of its own qualified experts") (emphasis added). Because the District Court is simply "unqualified" to decide "that the views of [R-CALF's] experts have more merit than those of [USDA's] experts," Greenpeace Action v. Franklin, 14 F.3d 1324, 1333 (9th Cir. 1992), R-CALF cannot possibly prevail on its claim that USDA's reliance on the SRM-removal requirement was arbitrary or capricious.

E. Mandatory Testing Of All Canadian Cattle Is Not An Effective Mitigation Measure.

Finally, the District Court erroneously concluded that USDA "fail[ed] to give consideration to the benefits and costs of mandatory testing" of all Canadian cattle, and "fail[ed] to explain to the public why these benefits do not justify mandatory testing." Op. 17. To the contrary, USDA specifically addressed comments recommending that all Canadian cattle be tested for BSE and explained why such testing is not "scientifically justified

or meaningful in the context of either human or animal health." 70 Fed. Reg. at 475.

As USDA explained, "the earliest point at which current testing methods can detect a positive case of BSE is 2 to 3 months before the animal begins to demonstrate clinical signs." Id. The incubation period, however, is "generally very long, on the average of about 5 years." Id. Thus, "[t]esting of individual animals, especially if it is performed on clinically normal animals at slaughter, is not in itself an effective risk mitigation measure for protecting public health." Id. As a result, "[m]aking this a criterion for minimal-risk regions would not contribute to human or animal health protection beyond the protection achieved by a statistically and epidemiologically valid surveillance plan." Id. at 475-476.

R-CALF has pointed to no scientific evidence suggesting that mandatory testing of all cattle is an effective mitigation measure. Nevertheless, the District Court rejected USDA's explanation for its decision, reasoning that, even though current testing methods cannot detect a positive case of BSE until 2 to 3 months before the animal begins to demonstrate clinical signs, "this does not mean that mandatory testing has no value, since it would detect some cases of BSE that would otherwise go undetected." Op. 17.

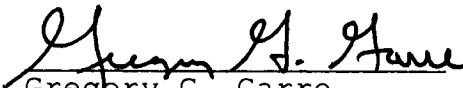
In so doing, however, the court impermissibly substituted its judgment for that of the agency. USDA examined the relevant

data and articulated "a rational connection between the facts found and the choice made," Baltimore Gas & Elec., 462 U.S. at 105: because mandatory testing of all cattle will not reliably detect BSE in cattle, especially those under 30 months of age, "[m]aking this a criterion for minimal-risk regions would not contribute to human or animal health protection." 70 Fed. Reg. at 475. That is all the APA requires, and the District Court erred in refusing to defer to USDA's considered judgment here.

CONCLUSION

For the foregoing reasons, the order granting the preliminary injunction should be vacated.

Respectfully submitted,



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April 21, 2005

CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 29(d) and 32(a)(7)(C), and 9th Cir. R. 32-1, I hereby certify that the attached amicus brief is monospaced, has 10.5 or fewer characters per inch, and contains not more than either 7000 words or 650 lines of text.



Gregory G. Garre

ADDENDUM

**Amici State Organizations and
Individual Cattle Producers**

1. Alabama Cattlemen's Association
2. Alaska Farm Bureau
3. Arizona Cattle Growers Association
4. Colorado Cattlemen's Association
5. Colorado Farm Bureau
6. Colorado Livestock Association
7. Florida Cattlemen's Association
8. Florida Farm Bureau Federation
9. Georgia Cattlemen's Association
10. Hawaii Cattlemen's Council
11. Idaho Farm Bureau Federation
12. Illinois Agricultural Association d/b/a
Illinois Farm Bureau
13. Illinois Beef Association
14. Indiana Beef Cattle Association
15. Indiana Farm Bureau, Inc.
16. Iowa Cattlemen's Association
17. Iowa Farm Bureau Federation
18. Kansas Farm Bureau
19. Kansas Livestock Association
20. Kentucky Cattlemen's Association
21. Louisiana Cattlemen's Association
22. Michigan Cattlemen's Association
23. Michigan Farm Bureau

24. Minnesota State Cattlemen's Association
25. Mississippi Cattlemen's Association
26. Missouri Cattlemen's Association
27. Missouri Farm Bureau Federation
28. Nebraska Cattlemen, Inc.
29. Nebraska Farm Bureau Federation
30. New York Farm Bureau, Inc.
31. North Carolina Cattlemen's Association
32. North Carolina Farm Bureau Federation, Inc.
33. Ohio Cattlemen's Association
34. Ohio Farm Bureau Federation, Inc.
35. Oklahoma Cattlemen's Association
36. Pennsylvania Cattlemen's Association
37. South Carolina Cattlemen's Association
38. Tennessee Farm Bureau Federation
39. Texas and Southwestern Cattle Raisers
40. Texas Cattle Feeders Association
41. Texas Farm Bureau
42. Utah Cattlemen's Association
43. Utah Farm Bureau Federation
44. Virginia Cattlemen's Association
45. Washington Cattle Feeders Association
46. Wisconsin Cattlemen's Association
47. Wisconsin Farm Bureau Federation
48. Bert Brackett, Idaho
49. Carl Crabtree, Idaho

50. Cevin Jones, Idaho
51. Dave Nelson, Idaho
52. Eric Davis, Idaho
53. Gene Davis, Idaho
54. James A. Little, Idaho
55. Joseph E. Tugaw, Idaho
56. K. Mark Nelson, California

CERTIFICATE OF SERVICE

I hereby certify that on this 20th day of April, 2005, two copies of the foregoing Brief for Amici Curiae National Cattlemen's Beef Association, et al. Supporting Defendants-Appellants and Vacatur were served by Federal Express on:

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